NOV 2 5 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number : K082253

A. Submitter:

Bodystat Ltd
P O Box 50
Douglas
Isle of Man
IM99 1DQ
BRITISH ISLES

Phone: +44-1624-629571
Fax: +44-1624-611544

Contact: I J Meeuwsen

Date Prepared: October 31st, 2008

B. Device Names:

Classification name	Impedance Plethysmograph
Common/usual name	Body Composition Monitor
Proprietary name	Bodystat 1500 Body Composition Monitoring Unit

C. Predicate Device:

The modified BODYSTAT®1500 Body Composition Monitoring Unit is substantially equivalent to previously cleared device, K951097, Bodystat 1500 Body Composition Monitoring Unit.
The BODYSTAT®1500 Body Composition Monitoring Unit device is a hardware and software modification of the previously cleared device.

D. Device Description:

The Bodystat 1500 Body Composition Monitoring Unit is an impedance plethysmograph that uses bio-electrical impedance analysis (BIA) to measure the impedance of the flow of an electrical current through the body. The impedance of tissue is proportional to the amount of fluid in the tissue; water is low in fat tissues, thus fat tissue has a high impedance, and high in lean tissues, thus lean tissue has a high impedance.

In practice, a small constant current is passed between electrodes spanning the body and the voltage drop between electrodes provides a measure of impedance. Prediction

equations, previously generated by correlating impedance measures against an independent estimate of TBW (total body water), may be used subsequently to convert a measured impedance to a corresponding estimate of TBW. Lean body mass is then calculated from this estimate using an assumed hydration fraction for lean tissue; Bodystat uses a proprietary regression equation for this calculation. Fat mass is calculated as the difference between body weight and lean body mass.

E. Intended Use:

For the purposes of performing a non-invasive bio-impedance analysis (BIA) measurements on normal healthy human adults to determine their Body Composition status.

This device measures bio-electrical impedance when a 50 kHz signal is applied at specific locations on the subject. From this and the subject's age, gender, weight, height, waist and hip circumferences (optional), the device calculates the following estimated values: fat%, fat weight, lean%, lean weight, total body water%, total body water, dry lean weight, basal metabolic rate, basal metabolic rate/body weight ratio, average requirement (EAR), and actual body mass index and waist/hip ratio.

OPTIONAL ACCESSORIES: Bodystat (1) BODY MANAGER and (2) WELLNESS SOFTWARE PROGRAMS.
The **Body Manager Program** is ideal when a client returns to be tested in order to track their changes in body composition over a period of time.
The **Wellness Program** is ideal for first time assessments on subjects. The program's graphical presentations provide information on each of the specific measurements in an educational format.

F. Comparison with the Predicate Device:

The modified BODYSTAT®1500 Body Composition Monitoring Unit is a hardware and software modification of the previously cleared Bodystat 1500. The modified Bodystat 1500 and the previously cleared Bodystat 1500 have the same intended use and use the same operating principle.

Based on the data and information presented here, the modified BODYSTAT®1500 Body Composition Monitoring Unit is substantially equivalent to the previously cleared Bodystat 1500 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2008

Mr. I. J. Meeuwsen
President
BODYSTAT® LIMITED
P.O. Box 50
Douglas, Isle of Man IM99 1DQ
BRITISH ISLES

Re: K082253
Trade/Device Name: BODYSTAT® 1500 Body Composition Monitoring Unit
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: November 14, 2008
Received: November 19, 2008

Dear Mr. Meeuwsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 4

Indications for Use

510(k) Number : K082253

Device Name: **BODYSTAT®1500 Body Composition Monitoring Unit**

Indications for Use:

For the purposes of performing a non-invasive bio-impedance analysis (BIA) measurements on normal healthy human adults to determine their Body Composition status.

This device measures bio-electrical impedance when a 50 kHz signal is applied at specific locations on the subject. From this and the subject's age, gender, weight, height, waist and hip circumferences (optional), the device calculates the following estimated values: fat%, fat weight, lean%, lean weight, total body water%, total body water, dry lean weight, basal metabolic rate, basal metabolic rate/body weight ratio, average requirement (EAR), and actual body mass index and waist/hip ratio.

OPTIONAL ACCESSORIES: Bodystat (1) BODY MANAGER and (2) WELLNESS SOFTWARE PROGRAMS.
The **Body Manager Program** is ideal when a client returns to be tested in order to track their changes in body composition over a period of time.
The **Wellness Program** is ideal for first time assessments on subjects. The program's graphical presentations provide information on each of the specific measurements in an educational format.

Prescription Use _____ (21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X__ (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082253